IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

Raymond Stevens and Arleen Stevens, Plaintiffs, v. Pacesetter, Inc., d/b/a St. Jude Medical Cardiac Rhythm Management Division, Defendant.	Case Number 3:07-cv-3812 **OPINION AND ORDER**

This matter is before the court on Defendant's motion to dismiss for failure to state a claim and, in the alternative, for summary judgment. Dkt No. 6. For the reasons set forth below, the motion is granted under Fed. R. Civ. P. 12(b)(6) and, alternatively, under Fed. R. Civ. P. 56.

Both aspects of Defendant's motion rest on the argument that Plaintiffs' claims are preempted by the Medical Device Amendments to the Food, Drug and Cosmetics Act ("MDA"). Initial briefing was completed on January 22, 2008.[1] The matter became ripe for resolution shortly thereafter when the court denied Plaintiffs' motion to remand. *See* Dkt Nos. 20 (requiring Plaintiffs to respond to the motion to dismiss but indicating that the motion to remand would be resolved prior to consideration of the motion to dismiss) & 35 (denying motion to remand).

This court, nonetheless, deferred resolution of Defendant's motion in anticipation of an imminent decision from the United States Supreme Court in a case which raised many of the same issues. *See* Dkt No. 40. That decision was issued on February 20, 2008. *Reigel v. Medtronic*, ___

[1] Defendant's motion, supporting memorandum, and exhibits were filed on November 26, 2007. Dkt No. 6. After some delay due to the pendency of a motion to remand, Plaintiffs responded on January 11, 2008. Dkt No. 27. Defendant filed a reply on January 22, 2008. Dkt No. 32.

U.S. ___, 128 S. Ct. 999 (2008). On March 17, 2008, this court invited supplemental briefing to address the *Riegel* decision. That invitation allowed the parties to supplement both their legal arguments and the factual record.[2] Only Defendant has responded to that invitation.[3]

For reasons explained in Defendant's supplemental memorandum, the decision in *Riegel* disposes of Plaintiff Raymond Stevens's claims except to the extent any claim might be construed as alleging a failure to comply with the *federal* standards which were established through the PMA process (*e.g.*, a claim for a failure to manufacture the device in accordance with the *federally* approved standards or to provide federally approved warnings). Plaintiff Arleen Stevens's claim for loss of consortium, although a distinct claim, relies on the same alleged wrongful conduct as supports Raymond Stevens's claims. *See Williams v. Lancaster County Sch. Dist.*, 631 S.E.2d 286, 294 (S.C. App. 2006) (noting that loss of consortium claim is an independent cause of action which requires proof that the injury results from intentional or tortious conduct); *see also* S.C. Code Ann. § 15-75-20. The loss of consortium claim is, therefore, foreclosed by *Riegel* to the same extent as Raymond Stevens's claims are foreclosed by that decision.

The complaint contains a few generic allegations of a manufacturing defect. These allegations do not, however, suggest that the particular alleged failure is a failure to manufacture the device *in accordance with federal standards*. Neither does the context of these or other allegations suggest a contention that Defendant failed to comply with the federally mandated standards for the

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[2] Discovery has been allowed to proceed despite the pendency of the motion to dismiss or for summary judgment. *See, e.g.*, Dkt No. 38 (amended scheduling order).

[3] A docket text order inviting comment on *Reigel* was entered on March 17, 2008, requesting supplemental briefing by March 25, 2008. As of entry of this order, no response had been received from Plaintiffs.

device's design, manufacture, and related warnings. Plaintiffs, in any event, have failed despite invitation to offer argument that any portion of their currently pled claims should survive the rule announced in *Reigel*. Neither have they sought to amend in light of *Reigel*. Under these circumstances, the court concludes that any currently pled manufacturing defect claims do not allege the narrow category of claim which might survive *Reigel*.

CONCLUSION

The complaint, therefore, is dismissed pursuant to Rule 12(b)(6) . To the extent reliance on Rule 12(b)(6) may be inappropriate, the court alternatively holds that Defendant is entitled to judgment under Rule 56.[4]

Because the court has relied primarily on Rule 12(b)(6), its ruling is *without prejudice* to Plaintiff's right to potentially pursue relief for a manufacturing (as opposed to a design) defect or other claim premised on Defendant's failure, if any, to comply with federal standards.[5] Dismissal is *with prejudice* as to any claim premised on standards contrary or in addition to the design,

[4] In their January 11, 2007 opposition memorandum, Plaintiffs argue that the matter is not appropriate for dismissal under Rule 12(b)(6) because a fact question was presented as to whether the device at issue had received premarket approval ("PMA") under the Medical Device Amendments. The complaint does not, however, allege that the device was marketed without such approval. Even assuming some question of fact may be inferred, Plaintiffs have offered no reasonable basis on which to question the authenticity of the documents offered by Defendant in support of its position that the device received PMA prior to the events at issue in this action. Neither do Plaintiffs adequately challenge Defendant's position that the court may take judicial notice of the PMA of the device in question which can be obtained from official federal sources including through an easily accessible government website.

[5] As Plaintiffs have not sought leave to amend their complaint to assert such a claim, despite having had an opportunity to respond to the *Riegel* decision, the court assumes that no facts which could support such a claim are presently known. This matter shall, therefore, be dismissed without leave to replead in this action.

labeling, warning, and other standards and requirements imposed as a result of the PMA of the device in question.

IT IS SO ORDERED.

S/ Cameron McGowan Currie
CAMERON MCGOWAN CURRIE
UNITED STATES DISTRICT JUDGE

Columbia, South Carolina
April 1, 2008

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